

Bldg./Room

OFFICIAL BUSINESS

AN EQUAL OPPORTUNITY EMPLOYER

HOPE60 101653067 1502 28 11/23/03
 FORWARD TIME EXP RTN TO SEND
 BOGOOD
 101 PARK AVE PL 40
 NEW YORK NY 10178-4499

RETURN TO SENDER

STANDARD

REC'D
DEC 2 2003

BEST AVAILABLE COPY



UNITED STATES POSTAGE
PRIME FIRST CLASS
PERMIT NO. 1000
NEW YORK, NY 10108
\$00.87
02 14
0504202245 NOV 14 A
MAILED FROM ZIP CODE 1003



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/458,033	06/01/1995	RICHARD M. HINDLEY	0132-138H	2675

7590 11/14/2003

HOPGOOD CALIMAFDE KALIL
& JUDLOWE
60 EAST 42ND STREET
NEW YORK, NY 10165

EXAMINER

GERSTL, ROBERT

ART UNIT	PAPER NUMBER
----------	--------------

1626

DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/458,033

Applicant(s)

HINDLEY ET AL.

Examiner

Robert Gerstl

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1626

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 17-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53 and 55 of U.S. Patent No. 5002953. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds use for hyperglycemia is claimed. Applicants' arguments have been considered and found not to be cogent. The compounds, subject, dose and method of administration of the instant claims are encompassed by the claims of U.S. Patent No. 5002953. The specification of U.S. Patent No. 5002953 discloses the specific embodiments that are encompassed by the claims. Thus the instant claims, in view of the claims and specification of U.S. Patent No. 5002953 are properly rejected.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1626

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

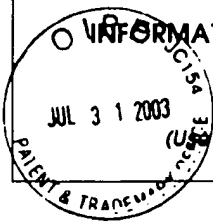
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Gerstl whose telephone number is 703 308-4531. The examiner can normally be reached on Mon.-Fri. (7-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe McKane can be reached on 703 308-4537. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4426 for regular communications and 703 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

Robert Gerstl
Primary Examiner
Art Unit 1626

RG
November 12, 2003

Form PT-D-1449	U.S. Department of Commerce Patent and Trademark Office	ATTY DOCKET NO B2368C4	SERIAL NO. 08/458.033
		APPLICANT Hindley, et al.	
		FILING DATE June 1, 1995	GROUP 1626

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation Yes No	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Black's Medical Dictionary, C.W.H. Havard, Eds., pp. 187-190 & 347 (1987). /
	The Textbook of Medicine, James B. Wyngaarden, Ed., pp. 1360-1381 (1988). /
	Fujita et al., "Reduction of Insulin Resistance in Obese and/or Diabetic Animals by 5[4-(1-methyleyclohexylmethoxy)benzyl]thiazolidine-2,4-dione (ADD-3878, U-63,287, Ciglitazone). A New Antidiabetic Agent," <i>Diabetes</i> 32(9), 804-810 (September 1983)
	Patent Certification Notice, July 11, 2003, Portions relating to U.S. 6,288,095
EXAMINER	DATE CONSIDERED
EXAMINER Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Sheet 1 of 2

Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office	ATTY. DOCKET NO. B2368C4	SERIAL NO. 08/458,033
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i>		APPLICANT Hindley, et al.	
		FILING DATE June 1, 1995	GROUP 1626

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	4,197,297	04/08/80	Weinstock			
	4,376,777	03/15/83	Kawamatsu et al.			
	4,725,610	02/16/88	Meguro et al.			
	5,002,953	03/26/91	Hindley			
	5,039,687	08/13/91	Efland et al.			
	5,194,443	03/16/93	Hindley			
	5,232,925	08/03/93	Hindley			
h	5,260,445	11/09/93	Hindley			
	5,478,852	12/26/95	Olefsky et al.			
	5,521,201	05/28/96	Hindley et al.			
	5,646,169	07/08/97	Hindley et al.			
	5,741,803	04/21/98	Pool et al.			

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
	EP 0 008203A1	02/20/80	EP O				
	EP 0 139421A1	05/02/85	EP O				
	EP 0 139421B1	4/27/88	EP O				
	EP 0 155845A1	09/25/85	EP O				
	EP 0 177353A2	04/09/86	EP O				
	EP 0 177353B1	04/11/90	EP O				
	EP 0 193256A1	09/03/86	EP O				
	EP 0 193256B1	04/05/89	EP O				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Berge, et al., Journal of Pharmaceutical Sciences, vol. 66, no. 1 (1977), pp. 1-19. "Review Article: Pharmaceutical Salts".
	Bottiger (Editor), Carlson et al. Journal of Internal Medicine, vol. 226, no. 4, October 1989, pp. 271-276, "Pronounced lowering of serum levels of lipoprotein Lp(a) in hyperlipidaemic subjects treated with nicotinic acid".

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet 2 of 2

Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office	ATTY. DOCKET NO. B2368C4	SERIAL NO. 08/458,033
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i>		APPLICANT Hindley, et al.	
		FILING DATE June 1, 1995	GROUP 1626

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	5,756,525	05/26/98	Hindley et al.			
	5,910,592	06/08/99	Pol et al.			
	6,288,095	09/11/01	Hindley et al.			
	US-2002-0049240A1	04/25/02	Hindley et al.			

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation Yes	Translation No
EP 0207581A2	01/07/87	EP				
EP 0208420A1	01/14/87	EP				
EP 0208420B1	09/18/91	EP				
EP 0306228A1	03/08/89	EP				
EP 0306228B1	11/17/99	EP				
EP 0419035A1	03/27/91	EP				
GB 2082584A	03/10/82	Great Britain				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Cantello, B.C.C. et al., Bioorganic & Medicinal Chemistry Letters 1994, vol. 4, no. 10, pp. 1181-1184, "The synthesis of FRL 49653 - a novel and potent antihyperglycemic agent".
	Momose, Y. et al., Chem. Pharm. Bull. 1991, vol. 39, no. 6, 1440-1445, "Studies on Antidiabetic Agents. X. Synthesis and biological activities of pioglitazone and related compounds".
	Sohda, et al., Chem. Pharm. Bull., vol. 30, no. 10, October 1982, pp. 3580-3600, "Studies on Antidiabetic Agents. II. Synthesis of 5-[4-(1-methylcyclohexylmethoxy)-benzyl]thiazolidine-2,4-dione (ADD-3878) and its derivatives".

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

in file:///c:/applications/5/5b2/534/ppe 1449 form.doc

U.S. COPENDING, COM MONLY OWNED PATENT APPLICATIONS

EXAMINER:

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office	ATTY. DOCKET NO. B2368C4	SERIAL NO. 08/458,033
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i>		APPLICANT Hindley	
		FILING DATE June 1, 1995	
		GROUP 1626	

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Black's Medical Dictionary, C.W.H. Havard, Eds., pp. 187-190 & 347 (1987).
	The Textbook of Medicine, James B. Wyngaarden, Ed., pp. 1360-1381 (1988).
EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	